AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,596	02/19/2002	Ronald W. Mink	030793-036100	2706

22204 7590 12/02/2005

NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,596	MINK ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 53-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 53-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 12 September 2005 has been received.

2. Claims 53-69 have been added. Claims 1 and 53-69 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 55-59, 65-67 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 65 are confusing because the position of the conjugate strip relative to the blocking strip is unclear.

Claim 57 is indefinite because of improper Markush grouping. A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). The inclusion in the alternative of DHEA binding glycoprotein is improper.

Claim 66 is vague with respect to the recitation of the housing is connected to the capillary matrix. How is the housing connected?

Claim 67, line 7 is incomplete.

Claims 68 and 69 are vague. It is recommended that "an apparatus" be replaced with "the apparatus" for clarity.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 55-58, 60-61 and 63-69 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Moorman (US 5,820,826).

Moorman discloses a device comprising a capillary matrix (26) having an exposed surface for receiving a test fluid (column 10, lines 22-23). A substrate pad (27) having assay reagents (column 10, lines 23-27), blockings strips including tape and a one-way flow regulating means are located between the capillary matrix and the

chromatography strip (column 10, lines 28-32). Moorman teaches that assay reagents may be dried into the pores of the blocking strip. (Column 11, lines 12-21). With respect to claims 63, 65 and 67, Moorman teaches that the apparatus is placed on an inert support or housing (column 5, lines 45-47 and column 11, lines 39-40), which meets the limitation that the chromatography strip extends into the cavity of the housing or the at least partially disposed in the housing. Moorman also teaches that additional features such as antibodies, signal inhibitors, buffers and so forth may be incorporated into the apparatus. (Column 11, lines 48-51) Moorman teaches that the device is capable of detecting analytes such as HIV antibodies, Rubella, etc. Moorman also teaches kits comprising the device, buffers and reagents for detection of analytes. (Column 26, lines 1-9).

Even though Moorman does not specifically disclose oral fluids, this limitation is seen to be an intended use of the claimed device and is not afforded patentable weight. Moorman also does not specifically call the collection matrix "paddle-shaped", however, since the specification does not specifically state the shape or composition of the "paddle-shaped" matrix, only that it has a certain surface area, the collection matrix taught by Moorman is seen to anticipate this limitation.

7. Claims 1, 53, 55-58, 60-61 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer (US 4,635,488) in view of Sangha (US 5,334,502) and de Zoeten et al (US 5,611,995).

Kremer discloses a sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in the open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the last mentioned end of the tube for contact with a fluid to be collected. The nib comprises a solid, nonfibrous, porous, water-wetable body having porosity sufficient for absorption of the fluid to be collected. The nib is a unitary molded plastic body made of polyethylene or polypropylene and is treated with a wetting agent to impart water-wettability. Column 2, line 48 through column 3, line 9. The device of Kremer is also provided with a cap for closing the open end of the tube and with an elongated, absorbent and rigid analysis element having an agent that undergoes an observable change upon contact with a substance to be detected in a body fluid sample. The analysis element also has a proximal end mounted in the cap, such that when the cap is in position closing the open end of the tube, the analysis element extends through the tube and its distal end is in fluid transferring contact with the inner extremity of the nib to receive and absorb fluid collected by the nib. The distal end of the analysis element may be anchored in the nib, or may comprise a body of porous material arranged for contact with the inner extremity of the nib so that transfer of the sample from the nib to the analysis element by absorption occurs only after collection of the sample by the nib has been completed. Column 3, lines 26-50. In one embodiment, the device having an analysis element, either in particulate form or strip form, also comprises an absorbent but hydrophobic body situated between the nib and the analysis element to prevent

premature transfer of samples to the analysis element. Column 3, lines 59-65, column 10, lines 53-68, and figure 16. Kremer discloses that the nib absorbs and retains a fluid sample by wicking or capillary action and should be contacted with, for example, the tongue until the nib is completely saturated with the body fluid; since a given porous nib has an essentially fixed fluid capacity, saturation assures collection of a sample of predetermined volume. Column 7, lines 7-23. Kremer discloses that porous nibs may be purchase from Porex Technologies. Column 5, lines 25-28. The device also comprises a transparent sidewall for visual observation of the color change. Column 8, lines 61-66.

Kremer differs from the instant claims in failing to teach a blocking strip comprising blocking agents and detergents or buffers.

Sangha discloses a method and device for saliva specimen collection comprising a capillary tube surrounding an absorbent pad. On top of the absorbent pad is a one-way barrier having indicator component. As saliva migrates or is wicked along the absorbent pad, it approaches and passes through the one-way barrier to interact with the indicator component. Once the saliva has passed upwardly through the barrier, the saliva is unable to migrate back through the barrier. Thus contact between the subject and the saliva that has interacted with the indicator is avoided. Column 9, lines 37-50. Sangha also discloses a test card for detecting analytes in a saliva sample comprising tretramethylbenzidine (TMB) dissolved in dimethyl formamide (DMF) or dimethyl sulfoxide (DMSO) and EDTA impregnated thereon and dried. Column 15, lines 13-27.

De Zoeten discloses an apparatus having a housing and holding device thereon for holding a test strip comprising a sample collector which can readily absorb test liquid, but also easily release the liquid under capillary transfer. The sample collector is made of material such as polypropylene, and to this material can be added, reagents such as buffering compounds to adjust the pH of the test liquid or compounds able to eliminate interfering substances present in the test liquid. Column 4, lines 40-59. De Zoeten discloses conventional blocking agents such as polyvinylalcohol, or human and bovine serum albumin. Column 7, lines 5-14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place reagents such as buffers and detergent taught by Sangha and de Zoeten in the device of Kremer because Sangha and de Zoeten teach that such reagents are well known in the art as providing the advantage of improving assay results by maintaining appropriate pH of the sample and dissolving interference material prior to contacting the sample with the test reagents.

A skilled artisan would have had a reasonable expectation of success in placing these reagents on the blocking strip of Kremer because Sangha teaches a blocking strip made of the same material as that of Kremer which can incorporate reagents such as dyes, and de Zoeten teaches adding buffering compounds to a sample collector (also made of the same material) to adjust pH of the test liquid. Therefore, absent unexpected results, these limitations are seen to be obvious in view of the teachings of Kremer as modified by Sangha and de Zoeten.

8. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer or Moorman in view of Sangha and de Zoeten as applied to claims 1 53, 55-58, 60-61 and 63-69 above, and further in view of Porex Technologies Catalog, 1995.

See the discussion of Kremer, Sangha and de Zoeten above. These references differ from the instant claim in failing to teach a capillary matrix having an average pore size from about 40 to 250μm.

Porex discloses porous plastics available in molded shapes, sheets, rods and tubes having an average pore size from 7 to greater than 250 micrometers. Porex engineers can also develop custom designs for specific use which will take into consideration strength, sample flow, durability and shape. See pages 1, 3, 8 and 24-25.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose a porous nib with the desired pore size such as taught by Porex for use in the device of Kremer or Moorman as modified by Sangha and de Zoeten because this parameters are dependent on the nature of the assay, i.e. samples to be tested and reagents involved. Therefore, a skilled artisan would have had a reasonable expectation of success in choosing from any of the disclosed nibs or to have nibs specification made to fit their needs. The selection of a specific material is generally dependent on the assay and the characteristics of the sample, therefore, absent unexpected or improved results, selection of nibs with specific pore sizes so as to

optimize the performance of a device is seen to be obvious in view of the teachings of Kremer or Moorman and Porex technologies.

9. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman as applied to claims 1, 55-58, 60-61 and 63-69 above, and further in view of Ching et al (US 5,120,643).

Moorman differ from the instant claims because it fails to disclose that the blocking agents are bovine serum albumin, deoxycholate or n-lauroyl sarcosine.

Ching, however, discloses that devices using labeled specific binding materials including colloidal particle and enzyme labeled materials which are dried onto a chromatographic medium in the presence of a meta-soluble protein are capable of being rapidly resolubilized in the presence of an appropriate solvent such as the sample (column 7, lines 3-10). Ching teaches impregnating solid substrate materials with meta-soluble proteins such as bovine serum albumin and detergents, e.g. sodium deoxycholate, etc. (Column 22, lines 25-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the meta-soluble proteins taught by Ching to the blocking means or substrate pad of Moorman because Moorman teaches that additional features may be incorporated into the apparatus including antibodies, signal inhibitors, buffers and so forth (column 11, lines 49-51) and Ching teaches that improved assay results is achieved using the meta-soluble agents. A skilled artisan would have had a reasonable expectation of success in adding the meta-soluble agents of Ching to the

device of Moorman because the addition of agents such as buffers and the like are well known in the art as indicated by Moorman and the choice of appropriate agents is chosen on the basis of the aim of the assay and the type of the analytes.

10. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman as applied to claims 1, 55-58, 60-61 and 63-69 above, and further in view of Ziegelmaier (US 6,632,628).

See the discussion of Moorman above. Moorman differs from the instant claims in failing to teach the detection of hepatitis. However, Moorman does teach that the analyte and the analyte specific receptors are chosen on the basis of the aim of the assay and discloses typical tests including assays for etiological agents for infectious diseases (column 23, lines 29-38).

Ziegelmaier discloses assays for etiological agents for infectious diseases such as HIV, rubella, hepatitis A and B, etc. See column 4, lines 1-6.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Moorman to detect analytes such as hepatitis as taught by Ziegelmaier because Moorman teaches that its device may be use to detect a variety of different analytes including etiological agents for infectious diseases and Ziegelmaier teaches that etiological agents such as hepatitis are well known in the art and can be detected using immunoassays. Furthermore, because Moorman teaches that the analyte and the analyte specific receptors are chosen on the

basis of the aim of the assay, one skilled in the art would have had a reasonable expectation of success in using the device of Moorman to detect hepatitis antigens or antibodies as taught by Ziegelmaier.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 53, 55-61 and 63-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-80 and 51-53 of copending Application No. 09/973,956. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a device for collecting and assay of analytes in oral fluids comprising a

housing, a collection pad coupled to a chromatographic strip having appropriate reagents. The device also comprises a blocking strips with blocking agents or buffers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641